REMARKS

Status of the Claims

Claims 1, 5-10, 13 and 15-20 are currently pending in the application. Claims 1, 2, 4-10, 13 and 14 stand rejected. The Examiner objects to claims 4-7. Claims 1, 5 and 13 have been amended as set forth herein. Claims 2, 4 and 14 have been cancelled herein. All amendments and cancellations are made without prejudice or disclaimer. New claims 15-20 have been added herein. No new matter has been added by way of the present amendments. Specifically, the amendment to claims 1 and 13 are supported by cancelled claims 2 and 4. Claim 5 is amended to recite the limitations of cancelled claim 2. New claims 15-20 are supported by, for instance, presently pending claims 5, 8-10 and 13. Reconsideration is respectfully requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 2, 4-10, 13 and 14 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (*See*, Office Action of December 5, 2006, at page 2, hereinafter "Office Action"). Claims 2, 4 and 14 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to these claims. Applicants traverse the rejection as to the remaining claims as set forth herein.

The Examiner states that claim 1 is indefinite because it does not clearly define what an antigen or antibody in the whole blood sample "is being assayed for." (*Id.*). The Examiner further states that "it is unclear as to whether the target antigen or antibody encompasses cell

surface antigens and intracellular antibodies present in the blood cell component of the whole blood sample." (*Id.* at pages 2-3).

Although Applicants do not agree that claim 1 is indefinite or unclear, to expedite prosecution, claim 1 has been amended herein without prejudice or disclaimer to recite, in part, "An immunoassay for assaying a soluble target antigen or antibody present in a whole blood sample." Thus, as amended, it is clear that claim 1 is directed to assaying a soluble target antigen or antibody. One of ordinary skill in the art, especially in the context of the present specification, would understand that the meaning of these terms includes only those antigens or antibodies that are soluble.

Additionally, part (g) of amended claim 1 recites that the claim is directed to obtaining a corrected concentration of soluble target antigen or antibody.

The Examiner further states that step (d) of claim 1 is ambiguous for "failing to define how the concentration of the target antigen or antibody is being obtained." (*Id.* at page 3).

Although Applicants do not agree that claim 1, part (d) is indefinite, to expedite prosecution, claim 1 has been amended without prejudice or disclaimer to also recite, in part, "(e) calculating a degree of agglutination from the number of the unagglutinated insoluble carrier particles and the number of the agglutinated insoluble carrier particles; (f) converting the degree of agglutination into a concentration of the soluble target antigen or antibody in the whole blood sample using a calibration curve showing a relationship between a degree of agglutination and a concentration of soluble target antigen or antibody." Applicants believe that this amendment adequately addresses the Examiner's concerns because parts (e) and (f) of amended claim 1

adequately explain to one of ordinary skill in the art how to calculate the concentration of the target antigen or antibody.

The Examiner also states that claim 1, part (e) is ambiguous for reciting "correcting the concentration . . . according to the number of blood cells." (*Id.*). The Examiner states that part (e) of claim 1 "fails to specifically define how the concentration of the target antigen or antibody is being corrected, in relation to the blood cells." (*Id.*).

Although Applicants do not agree that claim 1, part (e) is indefinite, to expedite prosecution, claim 1 has been further amended without prejudice or disclaimer to recite, in part, "(g) obtaining a corrected concentration of the soluble target antigen or antibody based on the following formula: C = CO / (1-B-A), wherein C is a corrected concentration, CO is the concentration of the soluble target antigen or antibody present in the whole blood sample, B is the number of blood cells and A is a constant." Applicants believe that this addition to claim 1 adequately addresses the Examiner's concerns about obtaining the corrected concentration since it explains how the corrected concentration is obtained.

The Examiner states that claim 5 is indefinite because it does not "clearly define what antigen or antibody in the whole blood sample is being assayed for." (*Id.* at page 4). The Examiner further believes that claim 5, step (d) is indefinite because it does not "define how the concentration of the target antigen or antibody is being obtained." (*Id.*). Additionally, the Examiner states that claim 5, step (e) is ambiguous because claim 5 does not "specifically define how the concentration of the target antigen or antibody is being corrected." (*Id.* at page 5).

Although Applicants do not agree that claim 5 is indefinite, to expedite prosecution, claim 5 has been amended herein without prejudice or disclaimer, in a manner similar to that of

claim 1. That is, claim 5 has been amended to recite additional parts which are believed to fully address the Examiner's concerns in a similar manner in which similar amendments to claim 1 have addressed similar issues with respect to various parts of claim 1.

Claim 13 is similarly rejected by the Examiner because claim 13 does not define "whether the target antigen or antibody encompasses cell surface antigens and intracellular antibodies present in the blood cell component of the whole blood sample." (*Id.*).

Although Applicants do not agree that claim 13 is indefinite, to expedite prosecution, claim 13 has been amended herein without prejudice or disclaimer, in a manner similar to that of claim 1. That is, claim 13 has been amended to recite additional language which are believed to fully address the Examiner's concerns in a similar manner in which similar amendments to claim 1 have addressed similar issues with respect to various parts of claim 1.

Since no independent reasoning is provided for the rejection of dependent claims 6-10, dependent claims 6-10 are believed to be definite for, *inter alia*, depending from a definite base claim, claims 1 and 5.

Reconsideration and withdrawal of the indefiniteness rejection of claims 1, 5-10 and 13 are respectfully requested.

Rejections Under 35 U.S.C. § 102(b)

Claims 13 and 14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kosako, U.S. Patent No. 5,527,714 (hereinafter referred to as "Kosako"). (*See*, Office Action, at page 6). Claim 14 has been cancelled herein without prejudice or disclaimer, thus obviating the rejection as to claim 14. Applicants traverse the rejection as to claim 13 as set forth herein.

The Examiner states that Kosako anticipates the presently claimed invention as recited in claim 13. (*Id.* at pages 6-7).

Although Applicants do not agree that claim 13 is anticipated by Kosako, claim 13 has been amended herein without prejudice or disclaimer to recite the limitations of non-anticipated claims 2 and 4. Thus, amended claim 13 is not anticipated by Kosako because amended claim 13 recites limitations not disclosed by Kosako. (*See*, *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)).

Reconsideration and withdrawal of the anticipation rejection of claim 13 are respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Kosako & Moskowitz et al., U.S. Patent Application Publication No. 2001/0046685

Claims 1, 2, 9 and 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable presumably over Kosako in view of Moskowitz et al., U.S. Patent Application Publication No. 2001/0046685 (hereinafter, "Moskowitz et al."), although this is not explicitly stated by the Examiner at the bottom of page 7 of the Office Action. (*See*, Office Action, at pages 7-9). Claim 2 has been cancelled herein without prejudice or disclaimer thus obviating the obviousness rejection of claim 2. Applicants traverse the rejection as to the remaining claims as hereinafter set forth.

The Examiner states that although Kosako does not disclose or suggest that the analyte sample is a whole blood sample and that the "spurious particles" are blood cells, Maskowitz et al. purportedly disclose or suggest these missing elements. (*Id.* at page 8).

Although Applicants do not agree that claim 1 is obvious in light of the combined disclosures of Kosako and Moskowitz et al., to expedite prosecution, claim 1 has been amended herein without prejudice or disclaimer to recite the limitations of non-obvious claim 4. Thus, since claim 4 is not rejected as being obvious in light of these references, it is believed that amended claim 1 is also non-obvious for the same reasons that claim 4 is non-obvious, since claim 1 now recites the limitations of now cancelled claim 4. (*See*, *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)).

Since no independent reasoning is provided for the rejection of dependent claim 10, dependent claim 10 is believed to also be non-obvious for, *inter alia*, depending from a non-obvious base claim, claim 1. That is, since claim 10 encompasses all of the subject matter of amended claim 1 by dependency, claim 10 also recites the limitations of non-obvious claim 4 and is also non-obvious at least for the same reasons that claim 4 is non-obvious.

Reconsideration and withdrawal of the obviousness rejection of claims 1 and 10 are respectfully requested.

Kosako & Moskowitz et al. & Steel et al., WO 98/20351

Claim 8 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Kosako in view of Moskowitz et al., and further in view of Steel et al., WO 98/20351 (hereinafter, "Steel et al."). (*See*, Office Action, at page 10). Applicants traverse the rejection as hereinafter set forth.

In addition to the Examiner's comments regarding the disclosures of Kosako and Moskowitz et al., the Examiner states that Steel et al. disclose or suggest the use of optical flow

particle analyzers that detect agglutination formation or the degree of non-agglutination by measuring forward scattered light and using particles having different sizes. (*Id.*).

As commented on, above, claim 1 has been amended herein without prejudice or disclaimer to recite the limitations of non-obvious claim 4. It is noted that neither claim 1 nor claim 4 are rejected as being obvious in light of the cited references. Furthermore, it is noted that claim 8 depends directly from now amended claim 1. Thus, dependent claim 8 is believed to also be non-obvious for, *inter alia*, depending from a non-obvious base claim, claim 1. That is, claim 8 is believed to be non-obvious at least because claim 8 encompasses all of the subject matter of amended claim 1 by dependency, and therefore because claim 8 recites the limitations of non-obvious claim 4. Thus, claim 8 is also non-obvious at least for the same reasons that claim 4 is non-obvious. (*See, In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)).

Therefore, reconsideration and withdrawal of the obviousness rejection of claim 8 are respectfully requested.

ENTRY OF AMENDMENTS

The amendments to the claims and new claims should be entered by the Examiner because the amendments are supported by the as-filed specification and because the new claims are supported by specification and at least original claims 8-10. Therefore, these changes do not add any new matter to the application. Additionally, the amendments and new claims should be entered since they comply with requirements as to form, and place the application in condition for allowance. Further, the amendments and new claims do not raise new issues or require a further search since the amendments and new claims incorporate elements from dependent

claims into independent claims and/or are supported by the as-filed specification. Finally, if the Examiner determines that the amendments and new claims do not place the application in condition for allowance, entry is respectfully requested since they certainly remove issues for appeal.

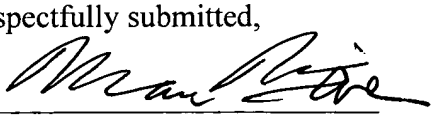
CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: March 5, 2007

Respectfully submitted,

By 

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